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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Edwards Lifesciences LLC  
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Irvine, CA 92614

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/11/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/981,337

Applicant(s)

SHANNON ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 81-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 81-102 is/are rejected.
- 7) ☒ Claim(s) 103-105 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the PTFE graft having been expanded and **completely** sintered prior to assembly with the stent is not found in the written disclosure. Additionally, the specification fails to provide support for **melted** polymer particles.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 81,82,84,88-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (WO 95/05132) in view of Ding et al. (5837313). Fig. 6 shows a cylindrical stent **10** formed with a tubular covering **20**. Myers discloses that the tubular covering is porous PTFE, page 3, lines 14-15. Regarding claims 82,84, it can be construed that a polymer coating, such as FEP is on the stent since it contacts the stent and is placed over it by the co-axially disposed PTFE graft, page 7, lines 10,12,21-24. However, Myers does not disclose the PTFE graft material is a plurality of concentric layers. Ding et al. teach to apply a plurality of layers to the stent, col. 3, lines 37-39, col. 5, lines 41-44. It would have been obvious to one of ordinary skill in the art to have multiple layers of graft material as taught by Ding et al. with the stent graft of Myers such that it is capable of providing therapeutic materials to the site of implantation and

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reduce restenosis. Regarding claims 88-90, Myers also discloses helically wrapping the stent with tape, with the tape having a width less than 1 inch, page 12, lines 24-26.

However, Myers et al. do not disclose applying 6-8 revolutions or layers of tape and in opposite directions. It would have been an obvious matter of design choice to modify the number of wrappings of tape and the directions applied on the stent, since applicant has not disclosed that using 8 layers or layering the tape in opposite directions provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the number of wrappings taught by Myers et al. or the claimed 8 layers and opposing directions in claim(s) 88-90 because both Myers and the claimed number of layers and application of these layers perform the same function of providing a blood impermeable lining.

Claims 91, 97-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (WO 95/05132) in view of McCrea et al. (6451047). Fig. 6 shows a cylindrical stent **10** formed with a tubular covering **20**. Myers discloses that the tubular covering is porous PTFE, page 3, lines 14-15. However, Myers does not disclose sintering the PTFE material. McCrea et al. teach to completely sinter the PTFE to assemble with the stent, col. 5, lines 49, 53-56. It would have been obvious to one of ordinary skill in the art to have a completely sintered graft material as taught by McCrea et al. and use with the stent graft of Myers such that it is better suited to bond to the stent and not separate. Regarding claims 97, 98 Myers also discloses helically wrapping the stent with tape, with the tape having a width less than 1-inch, page 12, lines 24-26.

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However, Myers et al. do not disclose applying 6-8 revolutions or layers of tape and in opposite directions. It would have been an obvious matter of design choice to modify the number of wrappings of tape and the directions applied on the stent, since applicant has not disclosed that using 8 layers or layering the tape in opposite directions provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the number of wrappings taught by Myers et al. or the claimed 8 layers and opposing directions in claim(s) 97-99 because both Myers and the claimed number of layers and application of these layers perform the same function of providing a blood impermeable lining.

Claims 91,92,100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallbracht (DE 3918736) in view of Pinchuk (5628788). Vallbracht discloses (Fig. 4) a stent 2 and a tubular PTFE graft 3 co-axially disposed with the stent. However, Vallbracht does not disclose a coating formed on the stent or that the graft is on the outer surface of the stent. Pinchuk teaches to place a polymer coating such as PTFE on the stent for adherence purposes, col. 6, lines 3,4,7-9. Pinchuk also teaches that the placement of graft materials can be reversed, col. 7, lines 31-34. It would have been obvious to one of ordinary skill in the art to use a coating on the stent as a substitute to stitching to adhere the graft and stent together as taught by Pinchuk with the stent-graft of Vallbracht in order to firmly adhere the two components together. The reversal of the PTFE graft to the outer layer would have been obvious since Vallbracht also disclosed an outer coating and Pinchuk teaches reversal of layers is relative to one skilled in the

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art. The PTFE would be more porous as the outer layer and improve in adherence to the vessel tissue.

Claims 93,101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallbracht '736 in view of Pinchuk '788 as applied to claims 92,100 above, and further in view of Parodi (5693087). Vallbracht as modified by Pinchuk is explained supra. However, Vallbracht in view of Pinchuk do not disclose the polymer coating as PTFE. Parodi teaches that PTFE coatings can be used on stent structures, col. 8, lines 54,55. It would have been obvious to use an alternative polymer coating such as PTFE as taught by Parodi with the stent graft of Vallbracht as modified by Pinchuk such that the coating aids in adhering the stent and seals the openings.

Claims 94,102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallbracht '736 in view of Pinchuk '788 as applied to claims 92,100 above, and further in view of Myers et al. (WO 95/05132). Vallbracht as modified by Pinchuk is explained supra. However, Vallbracht in view of Pinchuk do not disclose the polymer coating as FEP. Myers et al. teach that FEP coatings can be used to join a graft to a stent and not affect the porosity, page 7, lines 23,28-30. It would have been obvious to use an alternative adhesive such as FEP as taught by Myers et al. with the stent graft of Vallbracht as modified by Pinchuk such that the porosity of the graft material is not adversely affected.

Claims 83,85,86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '132 in view of Ding et al. '313 as applied to claims 81,82 above, and further in view of Banas et al. (5749880). Myers et al. as modified by Ding et al. is explained as

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before. However, Myers in view of Ding do not disclose the use of polymer particles between the stent and graft. Banas et al., teach the use of PTFE particles in solution for adhering the stent to the graft, col. 8, lines 64-67, col. 10, lines 2-8. It would have been obvious to use an alternative adhesive such as PTFE particles as taught by Banas et al. with the stent graft of Myers et al. as modified by Ding et al. such that the PTFE graft easily bonds with the similar adhesive material of PTFE particles. Regarding claim 83, the PTFE particles can be construed to be a substitute coating for the FEP that is on the PTFE graft of Myers as modified by Banas.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '132 in view of Ding et al. '313 as applied to claim 81 above, and further in view of McCrea et al. '047. Myers et al. as modified by Ding et al. is explained as before. However, Myers in view of Ding do not disclose sintered PTFE tape. McCrea et al. teach the use of a completely sintered PTFE graft for adhering with the stent, col. 5, lines 53-58. It would have been obvious to use completely sintered PTFE tape as taught by McCrea et al. with the stent graft of Myers et al. as modified by Ding et al. such that the PTFE graft easily bonds with the stent.

Claims 95,96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '132 in view of McCrea et al. '047 as applied to claim 91 above, and further in view of Banas et al. '880. Myers as modified by McCrea is explained supra. However, Myers in view of McCrea fail to disclose the use of polymer particles between the stent and graft. Banas et al. teach the use of PTFE particles in solution for adhering the stent to the graft, col. 8, lines 64-67, col. 10, lines 2-8. It would have been obvious

to use alternative adhesive means such as PTFE particles as taught by Banas et al. with the stent graft of Myers et al. as modified by McCrea et al. such that the PTFE graft easily bonds with the similar adhesive material of PTFE particles.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 9/12/03 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of 5928279 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Allowable Subject Matter***

Claims 103-105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 81,91,100 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

TC 3700, AU 3738

*Brian Pellegrino*

Bruce Snow

Primary Examiner

*[Signature]*